IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Purl, M.D., et al.,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	**Civil Action No. 2:24-cv-228-Z**
	§	
United States Department of Health and Human Services, et al.,	§	
	§	
Defendants.	§	

PLAINTIFFS' BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

SUMMARY

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") is a law about improving the efficiency of the nation's healthcare system by facilitating electronic recordkeeping. But, at the direction of President Biden, the Department of Health & Human Services ("HHS") has twisted it into a statute about "reproductive health care"—that is, abortion. HIPAA and its regulations are supposed to protect the privacy of *all* medical records while allowing disclosure for appropriate purposes, like reporting child abuse or protecting public health. But to undermine state laws that protect unborn children and mothers from abortion and older children from harmful "gender transition" procedures, HHS has put up special barriers around "reproductive health care" information. *See* "HIPAA Privacy Rule to Support Reproductive Health Care Privacy," 89 Fed. Reg. 32,976 (Apr. 26, 2024) ("the 2024 Rule"). And instead of respecting states' long-recognized authority to investigate crime and prevent abuse—as Congress instructed—HHS has created unlawful limits on state reporting procedures and investigations. This is unlawful.

A regulation like the 2024 Rule is final agency action subject to judicial review under the Administrative Procedure Act ("APA"), which empowers courts to vacate agency action that is contrary to law. 5 U.S.C. §§ 704, 706(2). As relevant here, agency action is contrary to law if it exceeds the agency's "statutory jurisdiction, authority, or limitations"; is "contrary to constitutional right, power, privilege, or immunity"; or is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A)–(C). The APA "empowers and commands courts to 'set aside' unlawful agency actions," and such "vacatur [will] render a challenged agency action void." *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 110 F.4th 762, 779 (5th Cir. 2024) (cleaned up).

This Court should vacate the 2024 Rule because it is statutorily and constitutionally unlawful as well as arbitrary and capricious.

The 2024 Rule is statutorily unlawful for three reasons. *First*, as the Court explained when granting a preliminary injunction, the 2024 Rule contradicts the restriction in its organic statute that HIPAA rules may not "limit" reporting procedures for abuse and public health. *See* Mem. Op. and Order, *Purl v. U.S. Dep't of Health & Hum. Servs.*, --- F. Supp. 3d ---, No. 2:24-cv-228-Z, 2024 WL 5202497, at *8–10 (N.D. Tex. Dec. 22, 2024), ECF No. 34.

Second, the 2024 Rule redefines statutory terms without statutory authority.

Third, the 2024 Rule illegally gerrymanders HIPAA around "reproductive health care" with no statutory basis. Congress would have spoken clearly had it granted HHS such substantial and politically fraught authority, but Congress did not do so. Thus both the major questions doctrine and the federalism canon foreclose HHS's reshaping of HIPAA. These absences of statutory authority create equally grave constitutional concerns. If HIPAA were construed to allow HHS to issue rules superseding state laws about public health investigations concerning abuse, abortion, and gender transitions for minors, the law would encroach both on federalism and on the Vesting Clause. Finally, the rule's expansive and ultimately incomprehensible standards alongside its criminal penalties raise serious vagueness concerns under the Due Process Clause.

The 2024 Rule is also arbitrary and capricious. HHS failed to sufficiently consider important aspects of the problem, such as that it forces doctors to make complex and nuanced legal judgments in the face of the Government's amorphous and insufficiently explained positions about federal law on "reproductive health care." Relatedly, HHS failed to reasonably explain how doctors and their practices are supposed to reach the 2024 Rule's many required legal conclusions given the Government's contradictory and confusing legal positions.

BACKGROUND

I. Carmen Purl, M.D. and Dr. Purl's Fast Care Walk-In Clinic.

Dr. Carmen Purl is a board-certified family practice physician. Purl Decl. ¶ 2, App. 001. She has been practicing medicine since 1986 and received her board certification in 1988. Purl Decl. ¶ 2, App. 001. She is the sole owner of Carmen Purl, M.D., PLLC, d/b/a Dr. Purl's Fast Care Walk In Clinic ("the Clinic"), through which she employs about 18 people. Purl Decl. ¶¶ 1, 3, App. 001. Dr. Purl and three nurse practitioners employed by her Clinic provide primary care to patients in Dumas, Texas. Purl Decl. ¶ 3, App. 001.

A significant proportion of patients at the Clinic are children, young women, and pregnant women. Purl Decl. ¶ 6, App. 002. During flu season, 10 to 20 children can come to the Clinic each day. Purl Decl. ¶ 11, App. 004. The Clinic provides services to many women seeking pregnancy tests, in part because a positive pregnancy test is a component of the applications for medical coverage under Texas's Medicaid for Pregnant Women and CHIP Perinatal programs. Purl Decl. ¶ 6, App. 002. The routine collection of information about a female patient includes information about the patient's last menstrual period, her age of menarche, number of pregnancies, and number of live births. Purl Decl. ¶ 7, App. 003. If the number of live births is less than the number of pregnancies, Dr. Purl inquires to determine whether the patient experienced a spontaneous abortion, more commonly known as a miscarriage, or whether the pregnancy was terminated by an induced abortion. Purl Decl. ¶ 7, App. 003. In Dr. Purl's experience, a thorough gynecologic history will include most or all of this patient information. Purl Decl. ¶ 7, App. 003.

Dr. Purl considers both a pregnant woman and her unborn child to be human persons, and her obligation as the treating physician is to care for both persons as her patients. Purl Decl. ¶ 6, App. 002. She believes that both mother and child are

entitled to care according to sound medical judgment and that both deserve the protection of the law. Purl Decl. ¶ 6, App. 002. She also believes that elective abortions and medical treatments trying to achieve "gender transition" of children harm patients' health and the public health. Purl Decl. ¶ 6, App. 002–003.

As professionals licensed by the State of Texas, Dr. Purl and her employees are subject to mandatory abuse reporting requirements under Texas law. Purl Decl. ¶ 4, App. 001. Failure to report child abuse or neglect within 48 hours may subject a Texas-licensed professional to criminal penalties, including incarceration. Purl Decl. ¶ 4, App. 001–002. Dr. Purl and her employees have similar obligations if they suspect abuse of a vulnerable adult, such as a patient with a disability or who is elderly. Purl Decl. ¶ 4, App. 001–002. Along with legal requirements, they have moral and ethical obligations to protect and advocate for their patients, including by reporting suspected abuse or crime. Purl Decl. ¶ 4, App. 002.

In her nearly 40 years as a practicing physician, Dr. Purl has encountered many minor patients who were abused or neglected, as well as some women and elderly victims. Purl Decl. ¶ 5, App. 002. She has encountered situations in which the likelihood of imminent abuse was so apparent that she caused the patient to remain at the Clinic while she called the local police to intervene. Purl Decl. ¶ 5, App. 002. In other situations, evidence of abuse was not immediately apparent but was discovered only later, such as upon review of X-rays showing old fractures or other indications of physical trauma. Purl Decl. ¶ 5, App. 002. It is common for Dr. Purl and clinic employees to encounter adolescent girls who are under the age of consent and are pregnant or report sexual activity. Purl Decl. ¶ 8, App. 003. Dr. Purl estimates she has treated hundreds of such girls and has delivered babies from mothers as young as 12 years old. Purl Decl. ¶ 8, App. 003. When Dr. Purl or her employees have suspected a patient was being abused or neglected, they have made reports to local law enforcement or Texas Child Protective Services ("CPS") in

accordance with Texas law. Purl Decl. ¶ 5, App. 002. Dr. Purl estimates she has personally treated more than 100 children who were the victims of sexual abuse, that Clinic personnel have treated hundreds of such victims, and that this shocking number of victims is typical of family medical practices. Purl Decl. ¶ 9, App. 003.

Dr. Purl and the Clinic cooperate with requests for patient records from CPS to facilitate its investigations of suspected child abuse and neglect. Purl Decl. ¶ 13, App. 004; Purl Supp. Decl. ¶ 3, App. 014. The demands from CPS are for the full, unredacted patient chart, whether or not the patient or his or her guardian consent to the disclosure. Purl Decl. ¶ 13, App. 004. Dr. Purl and the Clinic comply with these demands, as is their duty under Texas law. Purl Decl. ¶ 13, App. 004.

Compliance with the 2024 Rule would require Dr. Purl and the Clinic to incur costs to review and revise policies and train staff, and undertaking these activities would cause the Clinic to lose revenue and Dr. Purl to lose income. *See* Purl Decl. ¶¶ 15–18, App. 005–007. As HHS recognizes, the Clinic's policies and practices will have to be amended and updated to reflect the 2024 Rule's new definitions and special rules for "reproductive health care." 89 Fed. Reg. at 33,056. Dr. Purl estimates she would have to spend 5–8 hours to analyze the 2024 Rule and identify needed changes to the Clinic's policies and practices and to prepare training materials for staff, and then another 5–8 hours updating the Clinic's notice of privacy practices—not to mention the cost of legal counsel to provide guidance on the 2024 Rule's new requirements. Purl Decl. ¶ 18, App. 006. Dr. Purl's time spent on compliance-related activities carries an opportunity cost of between $360 and $480 per hour. Purl Decl. ¶ 18, App. 006.

The Clinic would also incur costs and lose revenue because clinic staff would need to be trained on how to comply with the 2024 Rule's new requirements. *See* 89 Fed. Reg. at 33,056. Dr. Purl estimates that online training would cost between $100 and $300 per person. Purl Decl. ¶ 15, App. 005. Conducting training for her

staff would require closing the clinic for "at least several hours," and every hour the clinic is closed costs at least $1,385 in patient fees, copays, and insurance reimbursements. Purl Decl. ¶ 16, App. 005.

II. HIPAA and the 2000 Privacy Rule

HIPAA was enacted to "improve portability and continuity" and "simplify the administration of health insurance." Pub. L. No. 104-191, 110 Stat. 1936, 1936 (1996). It includes privacy protections for patients' personal information. As important here, HIPAA provides that a regulated entity that "knowingly … discloses individually identifiable health information to another person, shall be punished" per HHS regulation. 42 U.S.C. § 1320d-6. As to the specifics of those privacy protections, Congress instructed HHS to make recommendations and then, if Congress did not act within a certain timeframe, to promulgate regulations. The privacy standards were to include "at least":

> (1) The rights that an individual who is a subject of individually identifiable health information should have.
>
> (2) The procedures that should be established for the exercise of such rights.
>
> (3) The uses and disclosures of such information that should be authorized or required.

42 U.S.C. § 1320d-2 note, "Recommendations With Respect to Privacy of Certain Health Information" (memorializing Pub. L. 104–191, title II, § 264, 110 Stat. 2033 (Aug. 21, 1996) (hereinafter "HIPAA § 264(b)")).

But Congress expressly limited HHS's rulemaking power concerning the authority of states to collect—and medical practitioners to provide—information about abuse and public health. *See id.* § 1320d-7(b). In § 1320d-7(b), Congress explicitly preserved this authority for states in a provision entitled "Public health." "Nothing in [HIPAA] shall be construed to invalidate or limit the authority, power,

or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention," Congress instructed. *Id.*

HIPAA defines "health information" broadly as encompassing "the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual." 42 U.S.C. § 1320d(4)(B). It does not carve out politically favored (or disfavored) procedures. It does not create tiers for different medical procedures. And it says nothing about abortion, gender transitions, or "reproductive health care."

In 2000, HHS adopted the "Privacy Rule," entitled "Standards for Privacy of Individually Identifiable Health Information," 65 Fed. Reg. 82,462 (Dec. 28, 2000). The Privacy Rule applies to covered entities, including "health care provider[s] who transmit[ ] … health information in electronic form." 45 C.F.R. § 160.102; *see id.* § 164.500. The Privacy Rule's "major goal" "is to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being."[1]

The Privacy Rule sets standards for when a covered entity can properly disclose protected health information ("PHI") without the patient's approval. Under the Privacy Rule, that includes disclosures:

- "for a law enforcement purpose to a law enforcement official," 45 C.F.R. § 164.512(f);
- "[i]n response to an order of a court" or "a subpoena, discovery request, or other lawful process," *id.* § 164.512(e)(1)(i), (ii);

---

[1] *See* HHS Office for Civil Rights ("OCR"), *Summary of the HIPAA Privacy Rule* 1 (May 2003), https://www.hhs.gov/sites/default/files/privacysummary.pdf.

- "to a health oversight agency for oversight activities authorized by law," *id.* § 164.512(d)(1); and
- to a "public health authority … for the purpose of preventing or controlling disease, injury, or disability," including "the conduct of public health surveillance, public health investigations, and public health interventions," *id.* § 164.512(b)(1)(i).

III. HHS conscripts HIPAA into its campaign against *Dobbs*.

In 2022, the U.S. Supreme Court reversed *Roe* and *Casey* and returned the power to regulate abortion "to the people and their elected representatives." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 259 (2022). The Court recognized the States' "legitimate interests" in promoting "respect for and preservation of prenatal life at all stages of development; the protection of maternal health and safety; the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability." *Id.* at 301 (cleaned up).

HHS and Secretary Becerra scorned *Dobbs*, calling it "unconscionable."[2] Secretary Becerra called abortion a "basic and essential part of health care," and boasted of his decades-long "fight for reproductive freedom for everyone, no matter who you are, *where you live* or how much you make."[3] Secretary Becerra committed HHS "to ensure every American has … the right to safe and legal abortion," and said he had "directed every part of my Department to do any and everything we can," and to "use every lever we have to protect access to abortion care."[4]

---

[2] Press Release, U.S. Dep't of Health & Hum. Servs., HHS Secretary Becerra's Statement on Supreme Court Ruling in *Dobbs v. Jackson Women's Health Organization* (June 24, 2022), https://perma.cc/89AZ-RFL4.

[3] HHS Press Release, *supra* note 2 (emphasis added).

[4] HHS Press Release, *supra* note 2.

Secretary Becerra's opposition to *Dobbs* led to a coordinated, agency-wide campaign to contort HHS's statutory authorities to promote abortion. He immediately took several actions that courts have since concluded exceeded HHS's authority. Three are significant here.

(1) Secretary Becerra issued a mandatory memorandum and letter from the Centers for Medicare & Medicaid Services ("CMS") that tried to force emergency rooms and doctors to perform abortions under the 1986 law the Emergency Medical Treatment and Labor Act ("EMTALA").[5] Judge Hendrix permanently enjoined this mandate as to the plaintiffs, the Fifth Circuit affirmed, and the Supreme Court denied HHS's request for review.[6]

(2) Through HHS's Office for Civil Rights ("OCR"), which issued the 2024 Rule challenged here, Secretary Becerra issued a first-of-its-kind "guidance" ordering pharmacies to dispense drugs for abortion purposes, claiming authority from Section 504 of the Rehabilitation Act of 1973.[7] Judge Counts rejected HHS's motion to dismiss a challenge to that mandate, declaring that the guidance was transparently issued to require abortion drugs in response to *Dobbs*. *See Texas v. U.S. Dep't of Health & Hum. Servs.*, 681 F. Supp.3d 665, 679 (W.D. Tex. 2023) ("Claiming now that the executive branch's actions are not about abortion is

---

5 *See* Mem. from CMS on Reinforcement of EMTALA Obligations specific to Patients who are Pregnant or are Experiencing Pregnancy Loss (QSO-21-22-Hospitals- UPDATED JULY 2022), (July 11, 2022) (revised Aug. 25, 2022), https://perma.cc/ND68-86SK.

6 *Texas v. Becerra*, No. 5:22-CV-185-H, 2023 WL 2467217 (N.D. Tex. Jan. 13, 2023) (amended judgment permanently enjoining enforcement of the memorandum against Texas and members of the plaintiff associations), *affirmed* 89 F.4th 529 (5th Cir. 2024), *cert. denied*, No. 23-1076, 2024 WL 4426546 (U.S. Oct. 7, 2024).

7 *See* HHS OCR, *Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services* (archived July 13, 2022), https://web.archive.org/web/20220713185710/https://www.hhs.gov/sites/default/files/pharmacies-guidance.pdf.

disingenuous at best."). OCR eventually revised the guidance to withdraw its abortion-drug mandate.[8]

And (3), Secretary Becerra signaled he planned to use the 28-year-old HIPAA statute to promote abortion. In June 2022, OCR issued "guidance" tying HIPAA to "comprehensive reproductive health care services, including abortion care," and citing the Secretary's opposition to *Dobbs*.[9] In January 2023, Secretary Becerra issued a report documenting HHS's broad efforts to promote abortion in opposition to *Dobbs*, including OCR's HIPAA guidance because it prohibits disclosure of information about abortion to pro-life states.[10] But because the 2000 Privacy Rule allowed doctors to disclose information for state investigations—consistent with HIPAA's statutory protection for state abuse and public health reporting laws—Secretary Becerra proposed the 2024 Rule. *See* "HIPAA Privacy Rule to Support Reproductive Health Care Privacy," 88 Fed. Reg. 23,506 (Apr. 17, 2023) ("Proposed Rule").

IV. The 2024 Rule creates a "reproductive health care" carve-out to promote abortion and gender transition.

HHS admits that the 2024 Rule is a reaction to "[t]he Supreme Court's decision in *Dobbs* [that] overturned *Roe v. Wade* and *Planned Parenthood of*

---

8 *See* HHS OCR, *Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies* (Sept. 29, 2023) ("Revised guidance: On September 29, 2023, OCR revised this guidance to clarify that the guidance does not require pharmacies to fill prescriptions for medication for the purpose of abortion."), https://perma.cc/S8ZB-WXRD.

9 HHS OCR, *HIPAA Privacy Rule and Disclosures of Information Relating to Reproductive Health* Care (June 29, 2022), https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/phi-reproductive-health/index.html.

10 HHS, *Marking the 50th Anniversary of* Roe*: Biden-Harris Administration Efforts to Protect Reproductive Health Care* (Jan. 19, 2023), https://perma.cc/HUC4-4WBL.

Southeastern Pennsylvania v. Casey, thereby enabling states to significantly restrict access to abortion." 89 Fed. Reg. at 32,987. As HHS puts it, *Dobbs* had "far-reaching implications for reproductive health care" that "increase[d] the likelihood that an individual's PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect." *Id.* at 33,978. On announcing the 2024 Rule, Secretary Becerra stated, "We're making it clear: you have the right to privacy—*Dobbs* did not take it away."[11]

The 2024 Rule created new restrictions on information disclosure by creating a new category of health care, "reproductive health care," and developing special rules for that category. 45 C.F.R. § 160.103. "Health care" is already a defined term in the Privacy Rule; it means "care, services, or supplies related to the health of an individual," and includes several listed categories, such as "[p]reventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care," and the "[s]ale or dispensing of a drug, device, equipment, or other item in accordance with a prescription." *Id.* ("*Health Care*" definition). But under the 2024 Rule, HHS inserted into the Privacy Rule a new definition of its new term, stating the phrase "[r]eproductive health care means health care … that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes." *Id.* ("*Reproductive health care*" definition). HHS says "reproductive health care," already defined to sweep in "all matters relating to the reproductive system," *id.*, should be "interpreted broadly and inclusive of all types of health care related to an individual's reproductive system" so that it "encompasses the full range of health care related to an individual's reproductive health," 89 Fed. Reg. at 33,005. The new definition includes medical interventions associated with "gender

---

[11] Secretary Xavier Becerra (@SecBecerra), X (Apr. 22, 2024, 11:32 PM), https://x.com/SecBecerra/status/1782432173665960400, App. 008.

identity." 89 Fed. Reg. at 32,989 n.163; *see also* Proposed Rule, 88 Fed. Reg. at 23,521 n.180. As a result, the 2024 Rule's new regime of special rules applies not only to abortions but also to gender transitions, even as to minors.

Having created this new category, the 2024 Rule imposes new and arcane limitations on disclosures of PHI about "reproductive health care" where the Privacy Rule would allow such disclosures if the PHI concerned any other kind of health care. *First* is the 2024 Rule's general limitation on sharing PHI with state officials and law enforcement. A covered entity may not disclose PHI sought:

> (1) [t]o conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care[;]
>
> (2) [t]o impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care[; or]
>
> (3) [t]o identify any person [for these purposes].

45 C.F.R. § 164.502(a)(5)(iii)(A).

Second, the 2024 Rule creates a multi-pronged overlay on this limitation. Disclosures are prohibited if reproductive health care was "lawful" in the state where performed or under federal law. Disclosure—even to respond to a court order or other process—are prohibited if:

> (1) [t]he reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided[;]
>
> (2) [t]he reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided[; or]

> (3) [t]he presumption [that the "reproductive health care" at issue was lawful] applies.

Id. § 164.502(a)(5)(iii)(B).

Third, the 2024 Rule creates a "presumption" that "reproductive health care" provided by another person was "lawful." *See id.* § 164.502(a)(5)(iii)(B)(3) & (C). The presumption is overcome only if (1) the covered entity has actual knowledge that the reproductive health care was not lawful or (2) the person requesting disclosure of PHI, *e.g.*, law enforcement, supplies "[f]actual information … that demonstrates a substantial factual basis that the reproductive health care was not lawful." *Id.* § 164.502(a)(5)(iii)(C)(2). When it applies, the presumption means PHI is non-disclosable even if the Privacy Rule would otherwise allow disclosures.

Fourth, the 2024 Rule requires public officials requesting PHI to swear the request is not being made for purposes prohibited by the 2024 Rule. *See id.* § 164.509(a). That is, public officials must provide an "attestation" that the request is not to investigate or impose liability on "any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care" that HHS deems "lawful." *Id.* § 164.502(a)(5)(iii)(A). For example, a police officer requesting information under "a court-ordered warrant," *id.* § 164.512(f)(1)(ii)(A), must present (along with the warrant) a "valid" (according to HHS) attestation, *id.* § 164.509(a).[12] And HHS's criteria for validity are voluminous and strict. *See* 45 C.F.R. § 164.509(b), (c). An attestation must include multiple kinds of information related to the request and its circumstances, and it places limits both on the covered entity's ability to rely on the attestation and on which public officials may draft it. The 2024 Rule even threatens state officials with federal criminal charges should

---

[12] An "attestation" is required for "health oversight activities," 45 C.F.R. § 164.512(d); for "judicial and administrative proceedings," *id.* § 164.512(e); for "law enforcement purposes," *id.* § 164.512(f); or when disclosure of PHI about a decedent is "to a coroner or medical examiner," *id.* § 164.512(g)(1).

they send a noncomplying attestation or if HHS deems the attestation to have been submitted "for a purpose prohibited" by the 2024 Rule. *Id.* § 164.509(c)(1)(iv) & (v).[13]

Fifth, the 2024 Rule places the risk of navigating this Rube Goldberg machine of disclosure rules on the covered entity. If the attestation is deficient, disclosure is prohibited by the 2024 Rule even if it would be required by state law—and the HIPAA-covered entity bears the risk HHS will later determine the attestation was deficient. *See id.* § 164.509(a)(2).

The 2024 Rule makes additional changes to support its new regime to limit PHI disclosures about reproductive health care. It narrows a provision that previously allowed disclosures of PHI by limiting disclosures to times when a response is "required by law." *Id.* § 164.512(f)(1)(ii)(C). Previously, information could be provided in response to an "administrative request" even if not required. *See id.* § 164.512(f)(1)(ii)(C) (2016). In other words, unless compliance is mandatory, the 2024 Rule prohibits disclosure.

The 2024 Rule also makes definitional changes intended to make it more difficult for states to investigate violations of their laws on abortion or gender transitions of minors. It defines "person" to exclude any unborn child. 89 Fed. Reg. at 33,062 (changes codified at 45 C.F.R. § 160.103) ("Person means a natural person (meaning a human being who is born alive)"). And it excludes abortion and gender-transition interventions from "public health" for purposes of Congress's instruction that HIPAA cannot place "limit[s]" on "public health surveillance," "public health investigation," and "public health intervention." *Id.* at 33,062–63 (changes codified at 45 C.F.R. § 160.103); *see* 42 U.S.C. § 1320d-7(b).

---

[13] *See also* HHS OCR, Model Attestation Form for a Requested Use or Disclosure of Protected Health Information Potentially Related to Reproductive Health Care, https://www.hhs.gov/sites/default/files/model-attestation.pdf.

Finally, the 2024 Rule allows disclosure of PHI about reproductive health care in one notable situation: it does not "prevent regulated entities from using or disclosing PHI [ ] defend[ ] themselves or others against allegations that they sought, obtained, provided, or facilitated reproductive health care." 89 Fed. Reg. at 33,011 (describing 45 C.F.R. § 164.502(a)(5)(iii)(D)). In other words, doctors performing abortions or gender transitions on minors, and anyone else defending them, can disclose reproductive health care PHI. But doctors cooperating with public health or abuse investigations, such as Dr. Purl, may not.

V. This Court issues a preliminary injunction.

On the eve of the 2024 Rule's first compliance deadline, this Court issued a preliminary injunction prohibiting enforcement against Dr. Purl and the Clinic. 2024 WL 5202497, at *11 (Dec. 22, 2024), ECF 34. Defendants contested Plaintiffs' standing to sue and showing of irreparable harm, but this Court found both. *Id.* at *5. The Fifth Circuit has "resoundingly rejected the very arguments Defendants make here," the Court noted. *Id.* at *5–6 (citing *Rest. Law Ctr. v. U.S. Dep't of Lab.*, 66 F.4th 593, 599–600 (5th Cir. 2023)). "Plaintiffs allege the very compliance costs contemplated by Defendants themselves," and "Plaintiffs estimate[d] the specific costs they would incur from training and procedure updates." *Id.* Their evidence more than satisfied the requirement to show unrecoverable compliance costs that are neither speculative nor de minimis. *Id.* The Court also agreed that Plaintiffs would "risk violating state-law reporting mandates" if they complied with the 2024 Rule's limits on such reporting. *Id.* at *10 (explaining that "Plaintiffs would incur 'hardship' if forced to comply with the 2024 Rule or conflicting Texas 'child abuse' requirements," and "Congress explicitly forbade HIPAA and its regulations from placing Plaintiffs in such a bind"). That, too, is irreparable harm, the Court

explained. *Id.* So the Court found an injury-in-fact sufficient for Article III standing as well as irreparable harm. *Id.* at *6, *10.

The Court next concluded Plaintiffs are likely to succeed on the merits. "Congress mandated that HIPAA cannot be 'construed to invalidate or limit the authority, power, or procedures established under *any law* providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.'" *Id.* at *2 (cleaned up) (quoting 42 U.S.C. § 1320d-7(b)). This provision is a "broad rule of construction that directs judges, regulators, and all others to make sure to protect laws that provide for the enumerated public health activities." *Id.* (quoting Barbara J. Evans, *Institutional Competence to Balance Privacy and Competing Values: The Forgotten Third Prong of HIPAA Preemption Analysis*, 46 U.C. Davis L. Rev. 1175, 1200 (2013)). And the Court concluded that the plain meaning of "limit" extends beyond a complete prohibition. *Id.* at *8. Rather, dictionaries "agree that something is *limited* when restrictions, restraints, or curtailments are imposed." *Id.* So "laws that curtail or restrain the activity—even if the activity is not completely prohibited—*limit* the activity through imposing obstructions[.]" *Id.*

The Court held that the 2024 Rule impermissibly limits the "'procedures established under any law providing for the reporting of … child abuse.'" *Id.* (quoting 42 U.S.C. § 1320d-7(b)). For one thing, it "requires 'covered entities' to determine whether the relevant 'reproductive healthcare' was 'lawful' under the circumstances it was acquired." *Id.* They must "*presume* it was 'lawful' unless they know or are reasonably shown otherwise." *Id.* But the legality of "reproductive health care" is a question that has often "confounded Article III courts—never mind medical professionals." *Id.* at *9 (citing, *e.g.*, *Moyle v. United States*, 603 U.S. 324 (2024) (mem. op.)). So "[r]equiring a doctor or other 'covered entity' to navigate [the 2024 Rule's] requirements and make perplexing legal judgments necessarily 'limits'

reporting 'child abuse' as Texas law mandates." *Id.* "Even if Dr. Purl, without legal training, enforced the 2024 Rule perfectly" for every disclosure of PHI, "the 2024 Rule would still constitute a limit," the Court explained, because a "'limit' presents anytime a HIPAA regulation raises impediments, restraints, or curtailments to eventual disclosure." *Id.* at *10. Having found that the 2024 Rule conflicts with § 1320d-7(b), the Court did not need to reach Plaintiffs' other arguments for why the 2024 Rule is likely contrary to law.

The Court concluded the balance of interests and public interest favored preliminary relief. *See id.* After all, existing regulations "already protect[] reproductive healthcare information the same as *all other* sensitive medical information." *Id.* And "[i]f Defendants are concerned that denying *surplus* protection to 'reproductive health care' information will dissuade some patients, it is because select states have curtailed or banned select abortion services," as is their "constitutional purview." *Id.*

For all these reasons the Court issued a preliminary injunction barring Defendants from enforcing the 2024 Rule against Dr. Purl and the Clinic while this litigation proceeds. *Id.* at *11. The Court set a summary judgment briefing schedule, *see* ECF No. 38, and instructed the parties to address: (1) how *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), "affect[s] the constitutionality or legality of HIPAA *and* HHS's authority to issue the 2024 Rule"; (2) how the major questions doctrine and (3) nondelegation doctrine affect the same questions; and (4) whether the definition of "reproductive health care" is void for vagueness. 2024 WL 5202497, at *11, ECF 34.

ARGUMENT

I. Dr. Purl and the Clinic have standing to challenge the 2024 Rule.

"When a plaintiff is an object of a regulation there is ordinarily little question that the [agency's] action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it." *Tex. Med. Ass'n,* 110 F.4th at 773 (cleaned up). There is no question here.

Plaintiffs are directly regulated by the 2024 Rule and therefore have standing to challenge it. "Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements. So in those cases, standing is usually easy to establish." *Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024). This is the case here: the 2024 Rule restricts when Dr. Purl and the Clinic can make disclosures of PHI. That triggers an Article III injury-in-fact and a statutory right to challenge the rule under the Administrative Procedure Act. "A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. The 2024 Rule inflicts a legal wrong on plaintiffs because its limitations are illegal, and it adversely aggrieves them because they wish to disclose information on the same terms they have previously done under HIPAA and the Privacy Rule. But they cannot do so under the 2024 Rule unless they obtain judicial relief. Moreover, the 2024 Rule adversely affects and aggrieves Plaintiffs by requiring they take action such as amending policies and practices and training staff. *See* 2024 WL 5202497, at *6, ECF 34 ("Plaintiffs have provided more than sufficient evidence to find they … have a cognizable injury for standing."). And because the 2024 Rule is illegal, these compliance costs are a "legal wrong" of their own. 5 U.S.C. § 702.

Dr. Purl has submitted a supplemental declaration to correct an inadvertent error about the frequency of CPS requests for patient records that she and the Clinic have handled. App. 014–15. Dr. Purl has received and responded to approximately 10 to 12 such requests from CPS. Purl Supp. Decl. ¶ 3, App. 0014. That correction does not change the Article III standing analysis. Any time CPS requests PHI, covered entities must contend with the 2024 Rule's requirements and may be prevented from complying—and CPS requests are just one type of disclosure limited by the 2024 Rule. *See infra* Sec. II.A.2. Plaintiffs are the object of the regulation and will incur compliance costs, which HHS concedes. This makes standing "easy to establish." *All. for Hippocratic Med.*, 602 U.S. at 382.

II. The 2024 Rule Is Contrary to Law.

A reviewing court must "hold unlawful and set aside agency action" that exceeds the agency's statutory authority. 5 U.S.C. § 706(2). The 2024 Rule is unlawful and should be vacated.

A. The 2024 Rule unlawfully limits disclosures about abuse and public health to state authorities.

1. HIPAA does not allow limits on disclosures to state officials for abuse and public health inquiries.

The 2024 Rule illegally restrains disclosures made for abuse reporting and public health investigations that the HIPAA statute expressly preserves for state authorities. For example, Dr. Purl and her staff have a duty to report suspected child abuse. *See* Tex. Fam. Code § 261.101(a); *see also* Tex. Hum. Res. Code § 48.051. And the 2024 Rule "limit[s]" the ability of doctors to comply with such laws. But HIPAA says HHS cannot "limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or

intervention." 42 U.S.C. § 1320d-7(b) (emphasis added). Thus, the 2024 Rule conflicts with HIPAA, because it imposes limits of a kind that the statute disallows.

As this Court has explained, the best reading of § 1320d-7(b) is that any hindrance or obstruction to reporting procedures is improper under HIPAA. As an undefined statutory term, the word "limit" carries its ordinary meaning. *See* 2024 WL 5202497, at *8, ECF 34 (citing *MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218 (1994)). The plain meaning of "'[l]imit,'" as the Court has explained, "does not mean that such restraints completely bar whatever is limited." *Id.* "Instead, laws that curtail or restrain the activity—even if the activity is not completely prohibited—*limit* the activity through imposing obstructions[.]" *Id.* (cleaned up).

Nor can HHS skirt HIPAA's rule of construction by claiming it may impose those same limits under a general grant of regulatory authority. The text of § 1320d-7 is straightforward: paragraph (a) sets forth the general preemption effect of HIPAA, and paragraph (b) says, "[n]othing in this part" shall impose limits on state abuse and public health reporting laws. "Nothing" means nothing, including HIPAA's general grant of authority for the Secretary to issue regulations and its general preemption provision in paragraph (a). So where HIPAA says the Secretary may propose regulations governing "[t]he uses and disclosures of [health] information that should be authorized or required," HIPAA § 264(b), that part of the statute is subject to § 1320d-7(b) no less than any other.

2. The 2024 Rule's incomprehensible standards add layers of limits that violate HIPAA.

Thus understood, the 2024 Rule creates many "limits" on reporting. To start, HHS admits covered entities considering disclosure will have to "screen requested PHI for whether it contain[s] information potentially related to reproductive health care." 89 Fed. Reg. at 33,060. Without the 2024 Rule, a doctor could simply produce

the PHI in compliance with state-law reporting procedures. Conducting this new screening is an obstruction to reporting, even if the PHI ultimately may be disclosed. That is a "limit." And the necessary screening will be extensive. The 2024 Rule uses a broad definition of "reproductive health care," so many patients' records include information falling within the "potentially related" universe. *See supra* at 11–12; 45 C.F.R. § 160.103 (2024); 89 Fed. Reg. at 33,005.

The screening obligation is not the only impermissible limit. If any PHI *could be* related to reproductive health care, the 2024 Rule "requires 'covered entities' to determine whether the relevant 'reproductive health care' was 'lawful' under the circumstances it was acquired." 2024 WL 5202497, at *8, ECF 34 (quoting 89 Fed. Reg. at 33,063). Even if that determination were simple, determining legality would be an obstruction to reporting, and thus an impermissible "limit."

But the determination is far from simple. Whether "reproductive health care" is "protected, required, or authorized by Federal law, including the United States Constitution," 42 C.F.R. § 164.502(a)(5)(iii)(B)(2), is a question that has confounded legislatures and courts for decades. That remains true even after *Dobbs*, as the Court has observed. 2024 WL 5202497, at *9, ECF 34. The federal government claims emergency rooms and doctors are required to perform abortions—even in violation of state law—under EMTALA.[14] HHS maintains guidance saying the *Roe* and *Casey* undue burden standard applies.[15] And the Government contends that the

---

[14] *See* Br. for the Resp't at 35, *Moyle v. United States*, Nos. 23-726, 23-727 (U.S. March 21, 2024) (arguing that EMTALA sometimes *requires* medical procedures "that violate state law"); Mem. from CMS, *supra* note 5, https://perma.cc/ND68-86SK.

[15] HHS OCR, *Guidance on Nondiscrimination Protections under the Church Amendments* (reviewed by OCR Feb. 3, 2024) (stating that "it is unconstitutional for a state to prohibit a patient from ending a pregnancy prior to fetal viability," "a state statute that has the effect of placing a substantial obstacle in the path of a woman's choice [to have a lawful abortion] cannot be considered a permissible

Equal Protection Clause negates laws like Texas' restriction on gender transition procedures on children. *See United States v. Skrmetti*, No. 23-477 (argued Dec. 4, 2024). Yet the 2024 Rule threatens HIPAA liability for disclosing information about, for example, an abortion that was illegal under state law but that HHS may decide was "required" by EMTALA or "protected" by its own (incorrect) guidance. Or for responding to a subpoena investigating illegal gender transition procedures that the Government claims are "authorized" by the Equal Protection Clause. *See* 2024 WL 5202497, at *9, ECF 34. "Requiring a doctor … to navigate these requirements and make perplexing legal judgments necessarily 'limits' reporting[.]" *Id.*

Worse, the 2024 Rule's new presumption of legality further limits reporting. If a patient's health information refers to "reproductive health care" provided elsewhere, doctors "must presume it was 'lawful' unless they know or are reasonably shown otherwise." *Id.* at *8 (quoting 89 Fed. Reg. at 33,063). As a presumption is meant to do, that puts "a thumb on the scale." *Ortez-Cruz v. Barr*, 951 F.3d 190, 199–200 (4th Cir. 2020) (describing a statutory presumption in these terms). If there is no indication of legality one way or the other, the scale tips to "lawful," and thus disclosure is prohibited under the 2024 Rule. And placing its thumb on the side of "lawful" abortion is exactly what HHS intended. *See* 89 Fed. Reg. at 33,034. But such a presumption is not reasonable, particularly in a state like Texas where abortion is generally prohibited and gender transition procedures cannot be performed on children. *See* Tex. Health & Safety Code §§ 161.702, 170A.002. Yet if a physician reasonably suspects abuse because of "reproductive health care" but there is no evidence to show whether the reproductive health care

---

means of serving its legitimate ends," and federally funded or provided abortions are also lawful), https://hhs.gov/conscience/conscience-protections/guidance-church-amendments-protections/index.html, App. 009–013. This Court observed that the guidance document was "reviewed and unmodified after *Dobbs*." 2024 WL 5202497, at *9, ECF 34.

at issue was lawful, disclosure is barred by the 2024 Rule. That means some cases of suspected abuse will go unreported.

The 2024 Rule also creates impermissible limits when state agencies request PHI to further abuse or public health investigations. Even when a requesting agency shares evidence that the "reproductive health care" was unlawful *and* satisfies the 2024 Rule's "attestation" requirement, doctors must second-guess the evidence and make their own determination—even a court order is not good enough. *See* 89 Fed. Reg.at 33,013–14 ("a regulated entity receiving the request for PHI must evaluate the facts and circumstances"), 33,032 (applying this to a court-ordered subpoena). Indeed, determining the adequacy of an "attestation" that PHI is not being sought for a prohibited purpose requires the same nuanced legal judgments, at it requires them twice over—first the requesting agent, and then the doctor, must run the information through the 2024 Rule. Even when its many obstructions are overcome and the information can be disclosed, reporting still has been limited.

As this Court observed, the 2024 Rule creates limits on abuse and public health reporting, but the statute allows *no* such "limit[s]." 42 U.S.C. § 1320d-7(b). That alone warrants vacatur of the 2024 Rule.

3. Under *Loper Bright*, HHS is not entitled to deference on what limits it may impose under § 1320d-7.

HHS is not entitled to deference on what "limits" are allowed by the rule of construction. HHS does not claim there is ambiguity in the word "limit" as used in § 1320d-7(b). Even if "limit" were ambiguous, the reviewing court's interpretation of the statute's "single, best meaning"—not the agency's view—would control. *See Loper Bright*, 603 U.S. at 400. And in any event, the 2024 Rule would be unlawful even if "limit" means only a complete prohibition on disclosure under the state laws set out in § 1320d-7(b). Among other things, HHS admits "situations may arise

where a regulated entity reasonably determines that reproductive health care was lawfully provided, while at the same time, the person requesting the PHI (e.g., law enforcement) reasonably believes otherwise." 89 Fed. Reg. at 32,993. In those cases, the 2024 Rule forbids disclosure. *Id.* The 2024 Rule says that so long as the reporting doctor believes the "reproductive healthcare" was lawful—or there is no factual showing one way or the other—disclosure is prohibited. That "limits" reporting, which strays from the statute.

That HIPAA grants HHS authority to issue rules does not constitute a delegation of authority to negate HIPAA's anti-preemption, no-limits provision for public health reporting. This is not a case in which Congress "expressly delegated to an agency the authority to give meaning to a particular statutory term," in this case, the term "limit." *Loper Bright*, 603 U.S. at 394 (cleaned up). The no-limits provision, § 1320d-7, contains no delegation of regulatory authority. Instead, regulatory authority to create the Privacy Rule is found in other parts of the HIPAA statute. *See* 42 U.S.C. § 1320d-2; HIPAA § 264(b). And none of those delegations "expressly" say that HHS may decide what a "limit" is, or how it might, despite § 1320d-7(b), curtail disclosures to states for abuse or public health inquiries. As Judge Thapar, writing for the Sixth Circuit, recently explained, the "statutes that *Loper Bright* cited as examples of delegations that may call for deference don't only have broad language. They pair that language with words that expressly empower the agency to exercise judgment." *Moctezuma-Reyes v. Garland*, --- F.4th ----, No. 23-3561, 2024 WL 5194988, at *2 (6th Cir. Dec. 23, 2024). Here, there is no pairing of unusually broad language with express empowerment of agency discretion. There is instead a simple reference to reporting procedures that protect state prerogatives, and a ban on the statute being used to infringe on those prerogatives.

Finally, under *Loper Bright*, "when an Executive Branch interpretation was issued roughly contemporaneously with enactment of the statute and remained

consistent over time" it might be entitled to respect in interpreting the law. 603 U.S. at 370. The problem for HHS is that gerrymandering HIPAA to make special rules for abortion and gender transitions was not contemporaneous with HIPAA's enactment. Rather, the 2024 Rule was issued 26 years after HIPAA. This history garners no respect for the 2024 Rule as an interpretation of the statutory text.

In short, far from justifying the 2024 Rule, *Loper Bright* prevents HHS from receiving deference for its novel interpretation of HIPAA.

B. The 2024 Rule unlawfully redefines statutory terms.

1. The rule unlawfully redefines "person."

The 2024 Rule enacts a definition of "person" not authorized by HIPAA or the Dictionary Act. It declares that "person" means a "natural person (meaning a human being who is born alive)." 89 Fed. Reg. at 33,062. By design, that excludes unborn children, and will prevent doctors from acting to protect their unborn patients from harm. That is unlawful.

HIPAA does not authorize HHS to issue its own definition of "person," much less to do so to exclude unborn children. Instead, Congress did not exclude unborn children from the meaning of the word "person," and it specified that the Dictionary Act's definition of "person" cannot "deny … any legal status or legal right applicable" to unborn children. 1 U.S.C. § 8(c).[16] *Dobbs* affirmed that states have the authority to consider the unborn as persons and afford them legal rights. Many states have done so. *See, e.g.*, Tex. Penal Code § 1.07(a)(26), (49). The Dictionary Act requires respecting those rights. *See* 1 U.S.C. § 8(c). But the 2024 Rule says, for example,

---

[16] The Dictionary Act (Chapter 1 of Title 1 of the United States Code) is the default rule governing the definition of words in statutes. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 707 (2014). The word "person" includes "individuals," 1 U.S.C. § 1, and "the words 'person', 'human being', 'child', and 'individual', shall include every infant member of the species homo sapiens who is born alive at any stage of development," *id.* § 8.

that an unborn child cannot be "a victim of abuse, neglect, or domestic violence" under HIPAA's terms. 89 Fed. Reg. at 32,997. So, for example, doctors cannot disclose information "to prevent or lessen a serious and imminent threat to the health or safety of" an unborn child. 45 C.F.R. § 164.512(j)(1)(i)(A).

This unlawful definition will hurt children even outside the abortion context targeted by HHS. Under the new definition, HIPAA will not allow doctors to report child abuse "where the alleged victim does not meet the definition of 'person' or 'child.'" 89 Fed. Reg. at 33,004. But many states' laws protect unborn children from abuse like dangerous substance use during pregnancy. *See, e.g.*, *Hicks v. State*, 153 So. 3d 53, 57–58, 66 (Ala. 2014) (interpreting Ala. Code § 26-15-3.2); Ariz. Rev. Stat. § 8-201; Ark. Code Ann. § 12-18-103; Colo. Rev. Stat. § 19-1-103; *see also* D.C. Code § 16-2301. But the 2024 Rule's new definition means doctors will violate HIPAA if they disclose PHI to report *any* abuse of an unborn child. Indeed, the agency's failure to consider this consequence of its restrictive definition of "person" independently renders the 2024 Rule arbitrary and capricious.

HHS could not lawfully "limit" state abuse-reporting procedures in this way. *See supra* Sec. II.A. Doing the same thing indirectly by defining unborn children out of HIPAA's disclosure allowances is just as improper. HHS cannot use "general rulemaking authority … to expand a congressionally imposed restriction." *Ciox Health, LLC v. Azar,* 435 F. Supp. 3d 30, 65 (D.D.C. 2020).

2. The rule unlawfully narrows the meaning of "public health."

Under the 2024 Rule's interpretation of "public health surveillance, or public health investigation or intervention," states cannot collect information to investigate or impose liability for "reproductive health care." 89 Fed. Reg. at 32,999. In other words, if a state law requires disclosure of information to investigate or

prosecute violations of a state's abortion laws, that law cannot count as "public-health" reporting protected from limitation by § 1320d-7(b).

This, too, violates HIPAA's anti-preemption provision, under which HHS cannot limit "any" state public health reporting procedures. 42 U.S.C. § 1320-7(b). But the 2024 Rule says HIPAA's preemption provision overrides state public health reporting procedures that HHS says aren't *really* about public health. This redefinition is a power grab, by which HHS is usurping the prerogative of states to protect public health using their traditional police power, including by restricting abortion as *Dobbs* said is in their purview. No text in HIPAA gives HHS authority to change what public health means, much less to do so for political purposes to favor some controversial procedures.

HHS admits that "a state might assert that investigating or imposing liability on persons for the mere act of seeking, obtaining, providing, or facilitating health care satisfies the definition of 'public health.'" 89 Fed. Reg. at 33,003. In reality, it is no stretch to say that gathering information about abortions "promote[s] the health of populations." *Id.* at 33,001–02. That is a view left to the states by *Dobbs*. But the 2024 Rule says that its new "interpretation would not supersede the definition of 'public health' in the context of public health surveillance, investigations, or interventions that the Department is adopting." *Id.* at 33,003. So even if a state includes such purposes in its own public health reporting, HHS will not treat those public-health laws as subject to HIPAA's no-limit provision.

HHS tries to justify its action by freezing state laws, including laws about abortion, as they were in 1996—when the *Roe* and *Casey* regime did not allow many laws restricting abortion. "When HIPAA was enacted," the 2024 Rule says, "the Model State Vital Statistics Act and Regulations, which is followed by most states, included distinct categories for 'live births,' 'fetal deaths,' and 'induced terminations

of pregnancy,' with instructions that abortions 'shall not be reported as fetal deaths.'" *Id.* at 33,000. According to HHS, that means "reporting of abortions … does not fall within the scope of state death reporting activities that Congress specifically designated as excepted from preemption by HIPAA." *Id.* The result—states may never treat deaths from induced abortion the same as other fetal deaths. And HHS does the same thing with regard to child abuse. *Id.* at 33,004.

Once again this is a backwards way of governing. HHS must derive its regulatory authority from what Congress gave it in HIPAA. *See West Virginia v. Env't Prot. Agency*, 597 U.S. 697, 723 (2022) ("Agencies have only those powers given to them by Congress."). HIPAA nowhere codified all constitutional doctrines touching medicine and all standards of care and practices as of the statute's enactment. Nor does it let HHS pick and choose from among those 1996 laws to impose different tiers of limits based on HHS's political inclinations. HIPAA is simply a law protecting patient health information generally. The reporting procedures that HIPAA protects from preemption are defined by state law. *Dobbs* determined that states have the prerogative to restrict abortions.

Moreover, in 1996 there was no legal dispute that states could protect children from procedures that irreversibly modify their bodies to try to change their sex. Yet the 2024 Rule does *not* attempt to embody 1996 law on that issue. Rather, it codifies the Biden administration's hope that the Supreme Court will create a constitutional right to gender transitions that overrides state laws protecting minors. *See United States v. Skrmetti*, U.S. No. 23-477 (argued Dec. 4, 2024). HHS's rationale citing the state of 1996 law is inconsistent at best.

The 2024 Rule's redefinition of public health to restrict state reporting presents a real threat to the public. Most states—including many with liberal abortion policies—require physicians or abortion facilities to report abortions to the state health agency or vital statistics agency. According to one pro-abortion

organization, 46 states and the District of Columbia have such reporting requirements.[17] *See, e.g.*, Ariz. Rev. Stat. § 36-2161; Ind. Code § 16-34-2-5; Iowa Code § 144.29A(1); Kan. Stat. § 65-445; 22 Me. Rev. Stat. § 1596(2); N.M. Stat. § 24-14-18; Okla. Stat. § 63-1-745.6; Or. Rev. Stat. 435.496; Tenn. Code § 68-3-505; Tex. Health & Safety Code § 245.011. The 2024 Rule will unlawfully limit such reporting procedures. At least one state acknowledges that its reporting requirements are meant, in part, "to monitor all abortions performed in [the state] to assure the abortions are done only under the authorized provisions of the law." Ind. Code § 16-34-2-5. But HHS says a physician would violate HIPAA by disclosing information "to law enforcement in furtherance of an investigation." 89 Fed. Reg. at 33,012. That contradicts § 1320d-7(b).[18] Dr. Purl and the Clinic, of course, do not perform abortions and would not have occasion to submit such reports. But the conflict between these state reporting requirements and the 2024 Rule shows the Rule's inconsistency with the statute.

It is the purview of states, not HHS, to decide what constitutes child abuse, which deaths will be recorded, and how to investigate threats to public health. HIPAA gives HHS no authority to do so. On the contrary, as explained above, HIPAA explicitly states that it cannot be used to preempt such state laws. 42 U.S.C. § 1320d-7(b). But the 2024 Rule superimposes its own view by excluding HHS's favored "reproductive health care" from such reporting.

---

[17] *See* Guttmacher Institute, *Abortion Reporting Requirements* (Sept. 1, 2023), https://www.guttmacher.org/state-policy/explore/abortion-reporting-requirements.

[18] Indeed, one Indiana physician has sued claiming the 2024 Rule preempts Indiana's abortion-reporting requirements. *See* Compl. for Declaratory and Inj. Relief, *Scifres v. Comm'r, Indiana Dep't of Health*, No. 1:24-cv-2262 (S.D. Ind. Dec. 23, 2024), ECF No. 1.

C. The 2024 Rule exceeds statutory authority by imposing special rules for abortion and "reproductive health care."

The 2024 Rule is unlawful not only because it limits public-health reporting, but also because it uses HIPAA to broach the subjects of abortion and gender transitions at all. The statute has nothing to say about those topics.

1. The major-questions doctrine precludes using HIPAA to create special rules about abortion or gender transitions.

The major-questions doctrine forecloses the 2024 Rule's special regime for "reproductive health care," a rule motivated by state-law restrictions on abortion and encompassing state laws on gender transitions for minors.

HIPAA is focused (as relevant here) on patient information and privacy generally, for all kinds of health care. It includes no reference to politically favored procedures, or to specific medical procedures at all. None of its text authorizes HHS to create different disclosure regimes for different kinds of health care.

HHS's use of HIPAA's generic text to gerrymander rules targeting highly politically charged procedures such as abortion and gender transitions raises even greater concerns about the agency's authority. Agencies may not create nationwide policy shifts using statutes that have nothing to do with that issue. For example, it was "not plausible that Congress gave EPA the authority to adopt" a regulation that would "force a nationwide transition away from the use of coal" based on statutory language lacking any such indication. *West Virginia*, 597 U.S. at 735. And the Supreme Court blocked the Biden administration's COVID vaccine regulation, citing both the purported statutory authority's focus on workplace safety, "not broad public health measures," as well as the "lack of historical precedent" for the rule. *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab.*, 595 U.S. 109, 117, 119 (2022).

There is no history of HHS using the Privacy Rule to create different tiers of health care. This rule did not arise until nearly 30 years after the statute was

enacted. It is the opposite of a longstanding and consistent interpretation that might suggest the statutory language anticipated such authority for the agency. To claim a modicum of precedent, HHS cites only one allegedly similar rule: its previous amendments creating special rules for how to handle psychotherapy notes. 89 Fed. Reg. at 32,977–78. But this is no precedent for using HIPAA to promote abortion. Psychotherapy *notes* are not a type of health care, they are a type of health *record*. They could concern any number of different health *conditions* related to any number of mental and physiological circumstances. Since HIPAA is a statute about health records, issuing rules about specific types of records is a far more proximate exercise than the 2024 Rule. Abortion, gender transition, and "reproductive health care," are not records—they are procedures, or as this rule states, they are a kind of "health care," namely reproductive health care. Information about those procedures can be reflected in many types of records. The 2024 Rule is therefore not about what HIPAA is about—records of information. And it is not analogous to the rule about psychotherapy notes. Instead, the 2024 Rule centers on a type of procedure or condition, not on a type of record or information. HIPAA does not make such a distinction.

With neither clear statutory text nor regulatory history to justify this rule, it triggers the skepticism the Supreme Court applies under the major-questions doctrine. The issues of abortion and gender transitions for minors are, alone or together, ones of vast political significance. Abortion spawned a 50-year culture war up and down the federal court systems, is the subject of countless state laws, and has been a central focus of presidential administrations and political campaigns (including the Biden administration's). Gender transitions for minors is similarly a contentious political issue that is the subject of state legislation and federal court litigation, including a case the Biden administration has taken to the U.S. Supreme Court. *United States v. Skrmetti*, No. 23-477 (argued Dec. 4, 2024). That HIPAA

regulates nearly every doctor and hospital in the nation and abortions and gender transitions have both significant costs and economic effects also implicates the economic significance of these issues.[19] Both require that before HHS can issue a rule like this one, Congress must first "speak clearly" to give HHS that authority. *West Virginia*, 597 U.S. at 716. HIPAA nowhere has that clear language, either to create different tiers of health care generally, or to do so for controversial issues like abortion, medicalized gender transition, and other sorts of "reproductive health care." The 2024 Rule deploys HIPAA as a weapon in hotly debated policy disputes that are properly decided by the people's representatives. Because HHS lacks statutory authority, the 2024 Rule exceeds agency authority and is contrary to law.

2. Using HIPAA to target "reproductive health care" upsets federalism.

The 2024 Rule's constraints on covered entities contradict HIPAA's preservation of state authority and respect for federalism. "Congress should make its intention clear and manifest if it intends to pre-empt the historic powers of the States." *Will v. Mich. Dep't of State Police*, 491 U.S. 58, 65 (1989) (cleaned up). "This plain statement rule is nothing more than an acknowledgment that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere." *Gregory v. Ashcroft*, 501 U.S. 452, 461 (1991). These structural principles protect "individual[s]," not just states. *Bond v. United States*, 564 U.S. 211, 222 (2011); *see also New York v. United States*, 505 U.S. 144, 181 (1992).

---

[19] *See, e.g.*, U.S. House Committee on Ways and Means, "REPORT: Abortion Costs U.S. Economy $6.9 Trillion," (June 16, 2022), https://waysandmeans.house.gov/2022/06/16/report-abortion-costs-u-s-economy-6-9-trillion/; Wesley Smith, The 'Gender-Industrial Complex' Makes Billions Annually, National Review (Aug. 28, 2024), https://www.nationalreview.com/corner/the-gender-industrial-complex-makes-billions-annually/.

To say the least, HIPAA does not provide clear notice of the disclosure restrictions created by the 2024 Rule. *See Bennett v. New Jersey*, 470 U.S. 632, 638 (1985). Indeed, HIPAA expressly reserves state power to obtain such information from medical practitioners. And if Congress could be said to have authorized HHS to issue this Rule, the lack of clear notice would create "grave constitutional concerns." *Mex. Gulf Fishing Co. v. U.S. Dep't of Com.*, 60 F.4th 956, 966–67 (5th Cir. 2023). Thus the 2024 Rule exceeds HHS's constitutional power and privilege under the APA.

3. If Congress did authorize HHS to undermine state laws with special treatment of "reproductive health care," that would raise grave constitutional concerns.

a) Non-delegation doctrine (Vesting Clause)

In HIPAA, Congress undoubtedly delegated some legislative power to HHS. "Government actions are 'legislative' if they have 'the purpose and effect of altering the legal rights, duties and relations of persons … outside the legislative branch.'" *Jarkesy v. SEC*, 34 F.4th 446, 461 (5th Cir. 2022), *aff'd*, 603 U.S. 109 (2024) (quoting *INS v. Chadha*, 462 U.S. 919, 942 (1983)). In HIPAA, Congress instructed HHS to address, among other things, "(1) [t]he rights that an individual who is a subject of individually identifiable health information should have"; "(2) [t]he procedures that should be established for the exercise of such rights"; and "(3) [t]he uses and disclosures of such information that should be authorized or required." HIPAA § 264(b).

If HHS were correct that HIPAA's delegation of legislative power allows the 2024 Rule, then HIPAA would have a serious non-delegation problem. "[A]ccountability evaporates if a person or entity other than Congress exercises legislative power." *Jarkesy*, 34 F.4th at 460. Congress may "obtain[] the assistance of its coordinate Branches" by delegating legislative power, but it must "lay down …

an intelligible principle" to guide the delegee. *Panama Refining Co. v. Ryan*, 293 U.S. 388, 420 (1935). That standard requires Congress to "clearly delineate[] the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority." *Mistretta v. United States*, 488 U.S. 361, 372–73 (1989).

HHS was given authority to determine what "uses and disclosures" of private information would "be authorized or required," HIPAA § 264(b), along with "a broad rule of construction that directs judges, regulators, and all others to make sure to protect laws that provide for the enumerated public health activities," Evans, *supra*, at 1200 (citing 42 U.S.C. § 1320d-7(b)). That rule of construction should guide the agency's decisionmaking. But the 2024 Rule nullifies the no-limits provision and redefines terms so that HHS, not the states, decides which public health reporting procedures count.

If § 1320d-7(b) means what HHS thinks it means, there's no intelligible principle—HHS would have unfettered discretion to say what "uses and disclosures of [private] information" are permitted, required, or barred. After all, other than in § 1320d-7(b), Congress said nothing about what "uses or disclosures" HHS should authorize or require, if any. Should a person have access to information about *himself*? Could guardians or personal representatives access PHI? What about other medical professionals? And what about law enforcement investigating a crime? Congress did not say. It left all these policy determinations to the agency. That unbounded discretion would be an unconstitutional delegation of legislative power. As a matter of constitutional avoidance, this Court should reject HHS's expansive view. *See Mex. Gulf Fishing*, 60 F.4th at 966–67.

HHS claims that HIPAA lets it slice up "health care" into any number of different categories it wants and create separately formulated rules to govern each. HHS claims HIPAA gives it authority to create such multi-level regimes even based on political motivations governing highly controversial procedures to override state

laws and drag the federal government into hotly contested national debates. HHS even claims the ability to change the very meaning of "public health" and of what a "person" is. That kind of power is inherently legislative and unbounded. There is no way a bureaucrat or member of the public could read the HIPAA statute and conclude what the outer limits are of how HHS could change the practice of medicine and the public regulation of it in the United States.

To be sure, the Fourth Circuit has held that HIPAA generally satisfies the nondelegation doctrine. *See S. C. Med. Ass'n v. Thompson*, 327 F.3d 346 (4th Cir. 2003). Its analysis is unpersuasive here. The court held HIPAA § 264(b)'s three instructions for HHS recommendations "amount to a statement of general policy by Congress … particularly when read in connection with" the statute's preamble setting out "the general purpose of HIPAA." *Id.* at 351 (cleaned up). It also found a "statement of general policy" in provisions identifying "whom the Privacy Rule was to cover," "what information was to be covered," "what types of transactions were to be covered," and timelines for compliance. *Id.*

That states the question at too high a level of generality, however. The question is not whether the agency has been given a general framework, but whether Congress provided guidance on the particular decision at issue. The Fifth Circuit in *Jarkesy* did not ask whether an intelligible principle governs the SEC's interpretation of securities fraud generally. *See* 17 C.F.R. § 240.10b-5 (implementing the Securities Exchange Act of 1934's prohibition on any "manipulative and deceptive device or contrivance" in the purchase or sale of a security). Nor did it ask about the SEC's decision to treat statements like Mr. Jarkesy's alleged misrepresentations as securities fraud. *See* 34 F.4th at 450 (describing allegations). Instead, the Fifth Circuit asked a specific question: whether Congress provided an intelligible principle to guide the SEC in "decid[ing] whether to bring securities fraud enforcement actions within the agency instead of

in an Article III court." *Id.* at 462. The Court determined Congress "said nothing at all indicating how the SEC should make that call in any given case." *Id.*

Similarly, here, Congress said nothing about how HHS should treat particular types of medical care, like "reproductive health care," for purposes of HIPAA. If Congress meant to give HHS authority to treat records differently depending on the type of medical care reflected, to write its own definition of the term "person," or redefine public health reporting without reference to background law, then Congress violated the non-delegation doctrine. The shocking breadth of authority HHS is claiming to justify the 2024 Rule would be a delegation of core legislative authority. In short, reading HIPAA to allow the 2024 Rule raises "grave constitutional concerns." *Mex. Gulf Fishing*, 60 F.4th at 966–67.

b) Vagueness (Due Process Clause)

A law is void for vagueness if it "(1) fails to provide those targeted by the statute a reasonable opportunity to know what conduct is prohibited, or (2) is so indefinite that it allows arbitrary and discriminatory enforcement." *McClelland v. Katy Indep. Sch. Dist.*, 63 F.4th 996, 1013 (5th Cir. 2023).

Several features of the 2024 Rule render it vague. To begin, it is not clear how a covered entity can discern what kind of patient information is "reproductive health care." The term "reproductive system," used in the new definition, may be understandable in and of itself. The definition, however, is not limited to PHI about the reproductive system. It encompasses health care that "affects the health" of a patient in "all matters" that even "relat[e]" to the reproductive system, *and* to "its functions and processes." Those expansive modifiers render the term vague.

The multiple layers of legal determinations imposed on doctors by the 2024 Rule exacerbate this vagueness. The 2024 Rule imposes additional indiscernible criteria, like whether HHS considers a reproductive health care service "lawful,"

whether the rule's "presumption" of lawfulness should or should not apply, and whether the many requirements of a public official's "attestation" are adequate. It also raises the serious risk that HHS will impose the rule based on "arbitrary and discriminatory enforcement" inherently connected to the politicized nature of abortion and gender transitions for minors. *McClelland*, 63 F.4th at 1013.

And the fact that violation of the 2024 Rule triggers criminal penalties heightens the Due Process vagueness concerns raised by this rule. *See Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 498–99 (1982) (the court exhibits less tolerance of vagueness in statutes with criminal penalties). The combined effect of HHS's expansive "reproductive health care" definition, the requirement to guess HHS's view whether a controversial procedure is "lawful," and uncertainty about whether the rule's presumption of lawfulness or its standards for adequate attestations apply, all suggest that the 2024 Rule is void for vagueness. *See* 5 U.S.C. § 706(2)(B) (agency action is unlawful where contrary to constitutional right).

III. The 2024 Rule is arbitrary and capricious.

The APA's arbitrary and capricious standard requires that agency action be "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). The 2024 Rule is neither. The 2024 Rule requires physicians and other healthcare providers to make complex legal judgments as a condition of HIPAA compliance. It is not reasonable to require doctors to resolve thorny legal questions that are the subject of fierce dispute even in the U.S. Supreme Court. And HHS failed to reasonably explain how it expects doctors to resolve those questions.

Under the 2024 Rule, HIPAA-covered entities must first determine whether an instance of "reproductive health care" was lawful to determine whether they may disclose information relating to that procedure. 89 Fed. Reg. at 33,063 (codified at

45 C.F.R. § 164.502(a)(5)(iii)). In making that legal judgment, the 2024 Rule requires that a physician like Dr. Purl presume that "reproductive health care" is lawful unless she has actual knowledge of unlawfulness or the requesting law enforcement agency supplies "[f]actual information … that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided." 45 C.F.R. § 164.502(a)(5)(iii)(C). In many instances, medical practitioners must also demand and assess an "attestation" to determine whether it meets the 2024 Rule's strict requirements. *Id.* § 164.509. These sorts of legal determinations are not within the scope of a healthcare provider's usual competence. And yet, if the health professional ends up being wrong, she could be subject to significant civil and criminal penalties.

At the same time, the 2024 Rule's presumption requires Dr. Purl and the Clinic to *ignore* what they do know about the law. In Texas, as in many other states, elective abortion is not legal. *See* Tex. Health & Safety Code § 170A.002. Neither is performing gender-transition procedures on children. *Id.* § 161.702. And it is unlawful to mail abortion-inducing drugs from outside the state. *See* 18 U.S.C. §§ 1461–62; Tex. Health & Safety Code § 171.063(b-1). The 2024 Rule is neither reasonable, nor reasonably explained, in forcing HIPAA-covered entities in Texas and similar states to presume an abortion, or gender-transition on a minor, is legal.

To keep complicating matters, HHS considers a procedure legal any time "[t]he reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided." 45 C.F.R. § 164.502(a)(5)(iii)(B)(2). HHS has claimed that EMTALA requires abortions that

would violate state law.[20] So to comply with the 2024 Rule, covered entities must engage in a complex legal analysis to determine whether reproductive health care—even if illegal under state law—was nonetheless "authorized by federal law."

HHS "entirely failed to consider [these] important aspect[s] of the problem." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The resulting scheme is insufficiently explained to satisfy the APA. The 2024 Rule does not explain or justify requiring such legal prognostication by HIPAA-covered entities. It gives no explanation or rationale for how a practitioner is supposed to determine whether the factual information provided with a request for information shows an abortion or gender transition was not legal.

For all these reasons, the 2024 Rule is arbitrary and capricious, and should be held unlawful and set aside for that independent reason as well.

IV. The proper remedy for an unlawful regulation is vacatur or a permanent injunction.

A. The APA requires vacatur of the 2024 Rule.

This Court should vacate the 2024 Rule entirely. Vacatur, or holding the rule unlawful and setting it aside, is the "statutorily prescribed remedy for a successful APA challenge to a regulation." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 374–75 (5th Cir. 2022). The 2024 Rule is unlawful for all the reasons addressed above, and that is all a claimant must show to obtain vacatur. *See Braidwood Mgmt., Inc. v. Becerra*, 104 F.4th 930, 952 (5th Cir. 2024), *cert. granted*, No. 24-316, 2025 WL 65913 (U.S. Jan. 10, 2025) ("[W]e do not read our precedent to require consideration of the various equities at stake" as would be required for obtaining a preliminary or permanent injunction); *accord Rest. L. Ctr. v. U.S. Dep't of Lab.*, 120 F.4th 163, 177

---

[20] *See* CMS Mem., *supra* note 5; HHS OCR, Guidance on Nondiscrimination Protections, *supra* note 15, App. 009–013.

(5th Cir. 2024) ("In such circumstances, [the Fifth Circuit's] default rule is that vacatur is the appropriate remedy." (cleaned up)).

Vacatur runs against the rule as such, not just as it applies to Dr. Purl and her Clinic. "[B]y its very nature" vacatur "is universal in scope because an unlawful regulation cannot be vacated as to only one party." *Texas v. Cardona*, No. 4:23-CV-00604-0, 2024 WL 3658767, at *47 (N.D. Tex. Aug. 5, 2024) (citing *Career Colls. & Schs. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024), *cert. granted in part, denied in relevant part, Dep't of Educ. v. Career Colls. & Schs. of Tex.*, No. 24-413 (U.S. Jan. 10, 2025)); *see also, e.g.*, *Ryan, LLC v. F.T.C.*, No. 3:24-CV-00986-E, 2024 WL 3879954, at *14 (N.D. Tex. Aug. 20, 2024).

And this relief needs to encompass the entire 2024 Rule, not just portions of it. This is not an omnibus rule that addresses several different topics, only one of which is reproductive health care. The entire 2024 Rule and all of its parts create, implement, and create cross-references and adjustments throughout the Privacy Rule to impose HHS's reproductive health care gerrymander and hobble states and doctors from sharing information on abortions, gender transitions for minors, and other situations encompassing reproductive health care. For example, the creation of the "reproductive health care" definition, the substantive limitations on disclosures potentially related to reproductive health care, the imposition of a presumption of legality, the changes in definitions of "person" and "public health," and the intricate criteria for valid "attestation," are all done in service of the same illegal effort to impose the administration's agenda. There are no aspects of the rule that serve independent goals. The entire rule should be encompassed in the Court's vacatur.

B. A permanent injunction would also be appropriate.

Alternatively, if the Court deems vacatur inappropriate, the Court should issue a permanent injunction against enforcement of the 2024 Rule. As shown above, plaintiffs are entitled to judgment on the merits. In addition, this Court has correctly concluded compliance with the unlawful 2024 Rule would cause irreparable harm and that the equities and public interest favor an injunction. That remains true. As the Court observed, existing regulations "already protect[] reproductive healthcare information the same as *all other* sensitive medical information." 2024 WL 5202497, at *10, ECF 34. Covered entities will risk violating their state-law reporting obligations if they comply with the 2024 Rule, and HIPAA enforcement action if they do not. Law enforcement will be hindered in investigating crime and abuse, and children and women will be put at risk.

There is no public interest in enforcing this illegal rule. HHS has no interest in covering up abuse and crime or interfering with states' authority over medical practice and public health, which includes the authority to restrict elective abortion. *Id*. And "[t]he public interest is served when administrative agencies comply with their obligations under the APA." *Clarke v. CFTC*, 74 F.4th 627, 643–44 (5th Cir. 2023) (quoting *N. Mariana Islands v. United States*, 686 F. Supp. 2d 7, 21 (D.D.C. 2009)). HHS cannot assert any equities that could offset the equities against enforcing this rule.

And because these factors are true for every Medicare-participating entity and in every state, injunctive relief should be universal. *See Career Colls.*, 98 F.4th at 255. An administrative agency cannot equitably be allowed to enforce an unlawful regulation against anyone. *Cf. Tex. Top Cop Shop, Inc. v. Garland*, No. 4:24-CV-478, 2024 WL 5049220, at *36 (E.D. Tex. Dec. 5, 2024) ("Given the extent of the violation, the injunction should apply nationwide.").

CONCLUSION

Dobbs returned "the authority to regulate abortion … to the people," 597 U.S. at 292, to be exercised through "the democratic process," *id.* at 269. Disappointed with the policies chosen by many Americans, through their legislatures, Secretary Becerra issued the 2024 Rule to undermine state abortion laws. The Court should grant Plaintiffs' motion for summary judgment; declare the 2024 Rule contrary to law; and vacate it under 5 U.S.C. § 706, or, in the alternative, issue a permanent injunction prohibiting enforcement.

Respectfully submitted this 17th day of January, 2025.

/s/ Natalie D. Thompson
Natalie D. Thompson
TX Bar No. 24088529
DC Bar No. 90026665
Matthew S. Bowman
DC Bar No. 993261
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Suite 600
Washington, DC 20001
Telephone: (202) 393-8690
Facsimile: (202) 347-3622
nthomspon@ADFlegal.org
mbowman@ADFlegal.org

Julie Marie Blake
VA Bar No. 97891
ALLIANCE DEFENDING FREEDOM
44180 Riverside Parkway
Lansdowne, Virginia 20176
Telephone: (571) 707-4655
Facsimile: (571) 707-4790
jblake@ADFlegal.org

Counsel for Plaintiffs